



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM

SUBJECT: Response to Comments From Uniroyal Chemical Company on the EFED Chapter of the Draft Reregistration Eligibility Document for Propargite

TO: Robert McNally, Product Manager 60 and
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FROM: Brian Montague, Team Leader
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THROUGH: Arnet Jones, Chief Environmental Risk Branch I
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Secondary Review: Kevin Costello

EFED's responses to potential errors mentioned in the *Uniroyal Response to EPA Draft Chapters and Other Reviews* are itemized below. EPA requested that Uniroyal Chemical Company provide comments on typographical, computational, mathematical, or other similar errors. All such errors identified by Uniroyal and pertaining to EFED's portion of the Draft Reregistration Eligibility Document were addressed. Comments regarding how the risk assessment was performed will be addressed during the upcoming comment period. In general, comments regarding EFED's portion of the risk assessment or assumptions made in EFED's assessment begin on page 24 of the comments.

1. **Uniroyal Chemical Company:** *page 9 - Registered Use Sites, Application Rates and Frequency of Application* Uniroyal wishes to bring to the Agency's attention the fact that proposed spray intervals for multiple treatments was included in a chart of current typical usage rates sent to EPA on 6/16/99. We did not find reference to these intervals in the draft RED chapters.

The minimum spray intervals provided to EPA by Uniroyal are:

Crop	Products	Min. Spray Intervals
Almonds	6E, 30W	21
Beans	Comite II	21
Christmas trees	6E, CR	28 (West) & 7 (East)
Citrus	Comite, CR	28
Corn, field	Comite II	42
Cotton	Comite II	21
Grapes	30W	21
Hops	6E, CR	21
Jojoba	Comite	21
Mint	Comite, 6E	21
Nectarines	30W	21
Peanuts	Comite, 30W	14
Potatoes	Comite, 6E	21
Roses	30W	14
Sugarbeets (seed)	Comite	21
Walnuts	6E, 30W	21
Non-bearing fruit & Nut	30W, CR	21
Non Bearings Nuts (in cotton & beans)	Comite	21
Non Bearing avocados	30W	21

EFED Response: EFED was not able to locate any mention of minimum intervals between applications on the latest versions of Comite, Omite or Ornamite labels accessed from Uniroyal and dated August 18, 1998. PHI and REI intervals are mentioned. Proposed label revisions are generally not employed in the ecological risk assessment process, unless it can be demonstrated that such changes are presently required for current uses. For most crop uses EFED assumed a 7 day interval between applications.

2. **Uniroyal Chemical Company:** *page 4 - Propargite Applications - Intervals* The minimum application interval is 14 days (peanut SLN), but for all other uses, the application interval ranges from a minimum of 21 days or longer.

EFED Response: EFED was not able to locate any mention of minimum intervals between applications on the latest versions of Comite, Omite or Ornamite labels accessed from Uniroyal websites and dated August 18, 1998. PHI and REI intervals are mentioned. Though these intervals do not currently appear to be on present labels, EFED is quite willing to consider the proposed label changes regarding the intervals at the close of the public comment period.

3. Uniroyal Chemical Company: Various Comments Regarding Drinking Water Values Calculated by EFED and/or Used by HED

page 11 - Water Resource Assessment

As noted in the preliminary human health risk assessment comments, the NAWQA drinking water database for 1992-1996 utilized over 8000 water samples. These samples were taken from both ground and surface waters, in areas that tend to have high pesticide use. Only 1 sample out of 3023 ground water samples contained detectable propargite residues (0.008 ppb), and less than 3% (175 out of 5196) surface water samples analyzed contained propargite residues (0.003 - 20 ppb). As shown below, the 20 ppb datapoint was the only sample containing propargite residues of this magnitude in surface water.

(%) of surface water samples with specified propargite residue
(total number of surface water samples = 5196)

<u>0.01 ppb</u>	<u>0.01-0.1ppb</u>	<u>0.1-1ppb</u>	<u>1-10 ppb*</u>	<u>≥10 ppb</u>
39	68	52	15	1
(0.8%)	(1.3%)	(1.0%)	(0.3%)	(0.02%)

* maximum propargite residue was 4 ppb

The extensive NAWQA water monitoring data shows that propargite residues in surface water are generally less than 1 ppb.

Drinking Water Comments(as contained in the HED Chapter)

page 5 - Both the acute and chronic dietary exposure analyses included drinking water in the assessment. Water monitoring data from over 8000 samples from the US Geological Survey National Water Quality Assessment Program (NAWQA) in 1992-1996 showed that propargite residues were rarely detected in groundwater. Only 1 sample out of 3023 ground water samples contained detectable propargite residues (0.008 ppb), and less than 3% (175 out of 5196) surface water samples analyzed contained propargite residues (0.003 - 20 ppb). It should be noted that use of the NAWQA database is conservative, since the NAWQA was designed to assess pesticides in source water and NAWQA data now available tend to come from areas of high pesticide use. Water samples are collected from freshwater streams, rivers, and aquifers, not potable water. These surface waters are further treated via chlorination, carbon filtration, or other methods. Therefore, propargite concentrations in actual drinking water would be expected to be substantially reduced. In addition, ten labeled uses of propargite were cancelled in 1996. Current propargite usage would have been decreased compared to 1992 - 1996, the years used in the NAWQA database. These factors would make the NAWQA database of over 8000 samples for propargite and the drinking water estimates even more conservative. Although the GENECC and SCI-GRO models are typically used as a screening tool for drinking water estimates, a more accurate and realistic (but still conservative) estimate for propargite is

obtained from use of the NAWQA database.

The weighted average (surface and ground source of drinking water) of propargite in drinking water was 0.013 ppb, assuming one-half limit of detection for all samples without detectable residues. The cancer risk from drinking water alone was estimated as 5.13×10^{-8} . A sensitivity analysis where zeros were substituted for non-detectable residues resulted in a cancer risk of 2.76×10^{-8} , indicating that almost half of the drinking water risk was attributable to non-detectable residues.

Using a more conservative approach, the average of all propargite residues in only surface water samples, assuming one-half limit of detection for samples without detectable residues, was 0.02 ppb. When zero is substituted for samples without detectable residues, the average residue was 0.014 ppb. These results are similar to the weighted ground and surface water average as used in the chronic dietary exposure assessment. Use of the entire NAWQA database from 1992 - 1996, or even only the surface water average, would be more appropriate than the narrow 2-year period defined by the Agency.

These data show that the chronic risk from surface and groundwater residues of propargite is negligible.

page 61 - The Uniroyal assessments include the risk from drinking water in the acute and chronic dietary exposure analyses. The analysis showed that for acute dietary exposure, the DWLOC for the three population subgroups examined exceeded by at least 35-fold the maximum value reported in the NAWQA water monitoring data. In the chronic dietary exposure analysis, average residues of propargite in drinking water based on the NAWQA data were 0.013 ppb, and that the risk contribution from drinking water was 2.76×10^{-8} (when zeroes were substituted for non-detects) to 5.13×10^{-8} (when half the LOD was substituted for non-detects). The aggregate exposure to potential propargite residues in both food and drinking water was 0.0000059 mg/kg bw/day, and is a negligible risk of 1.01×10^{-6} .

EFED Response:

EFED has reviewed the comments regarding the choice of NAWQA monitoring data and also the methodology used in the calculation of the recommended ground and surface water concentration numbers for use in drinking water assessments. As the comments do not reflect an actual error in calculations, but do reflect company position regarding how this type of calculation should be conducted and what input values should be included, the Agency will discuss these comments in greater detail during the upcoming 60 day comment period .

4. Uniroyal Chemical Company: Table 2 - Avian Reproduction

Avian reproduction endpoints (corrected for actual dietary concentrations) are:

bobwhite quail - LOAEC = 949.6 ppm; NOAEC = 288 ppm
mallard duck - LOAEC = 84.7 ppm; NOAEC = 43.2 ppm

EFED Response: The registrant is correct in that body weight (growth) for mallard females appeared to be affected at 84.7 ppm. Reproduction was not affected at this level but was affected at 288 ppm with a no effect level of 84.7 ppm. Error corrections in the appendices will be made. Chronic risk values for birds will be recalculated, but no change to overall risk presumptions for reproductive effects will result. Long term affect to growth will be at lower levels than that for reproductive effects.

Uniroyal Chemical Company: Table 3 - *Mammalian Acute Toxicity*

The acute oral rat LD₅₀ is 2639 mg/kg (MRID NO. 42857001). This study was conducted with 90.3% ai propargite.

EFED Response:

EFED will make corrections as noted to the mammalian effects table in the appendices. Any changes required in the calculation of risk quotients will be made in the EFED risk assessment portion of the document.

5. **Uniroyal Chemical Company: Table 4 - *Mammalian Chronic Toxicity***

The chronic toxicity LOAEL in females is 800 ppm and the NOAEL is 400 ppm. In males, the LOAEL is 400 ppm and the NOAEL is 80 ppm.

The % ai in the rat reproduction test is 87.2. The systemic LOAEL is 400 ppm and the NOAEL is 80 ppm. The offspring LOAEL is 800 ppm and the NOAEL is 400 ppm. The reproductive LOAEL and NOAEL are both >800 ppm (MRID NO. 41325401)

EFED Response:

EFED will make corrections as noted to the mammalian effects table in the appendices. Any changes required in the calculation of risk quotients will be made in the EFED risk assessment portion of the document.

6. **Uniroyal Chemical Company: Table 9 - *Estuarine/Marine Organism Acute Toxicity***

The 48 hr EC₅₀ to the quahog clam is reported as 110 ug/l, based on measured concentrations at zero time.

EFED Response: As noted in the data evaluation report for this study, the 80 ppb estimate was based on measured concentration data presented in the study submission in which approximately 42% degradation was observed over a 48 hour period in one concentration that was measured. Use of the zero hour measured concentration would not represent the average concentration to which the organisms were exposed during the entire study. The 0 hour and terminal(48 or 96 hour) hour measured concentrations for all test levels should be provided in acute studies where degradation of the test material is a factor. This enables calculation of mean exposure concentration estimates. See the study evaluation for further detail. EFED does not believe this estimate is an error and thus no change to the assessment will be made at this time.

7. **Uniroyal Chemical Company: Table 10 - *Non-Target Terrestrial Plant Seedling Emergence/Vegetative Vigor***

Comite (76.2% ai) was used in these tier 1 studies at 2.45 lb ai/A, and no growth effects were seen. We were notified on July 1, 1996 that the studies were upgraded to core status. The correct MRID Nos. for the studies are 438858-01 and 438858-02 (Aufderheide and Kranzfelder, 12/28/95).

EFED Response:The registrant is correct. Following submission of additional information regarding the seeds and watering methods used in these studies they were subsequently upgraded to core status and memo stating this is dated Jun. 28, 1998 (D226818). Corrections will be made to this table.

Appendix 4

Table A2. – Status of Ecological Effect Data Requirements for Guideline 72-4b.
The MRID number appears to be an error, as it is already referenced in 72-4a.

EFED Response:The 72-4a and 72-4b MRIDs should be 00126738 and 00126739, respectively. Table A2 will be corrected to reflect this.